

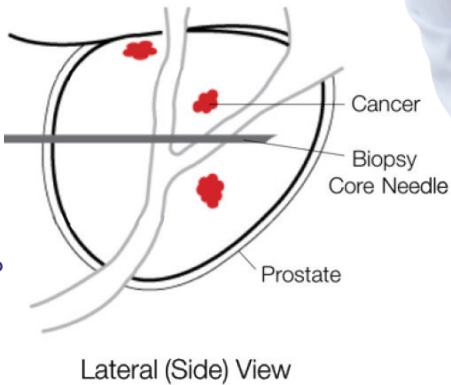
# 3 Things You Should Know Before Having a Prostate Biopsy

- 1. Prostate tissue samples taken during your biopsy procedure are reviewed by a pathologist who uses a microscope to examine your tissue for cancer cells
- 2. A standard prostate biopsy samples less than 1% of the entire prostate and your diagnosis is based only on the tissue sampled<sup>3</sup>
- 3. Because the biopsy provides limited information, your urologist may consider additional testing to determine if you're at risk for undetected cancer

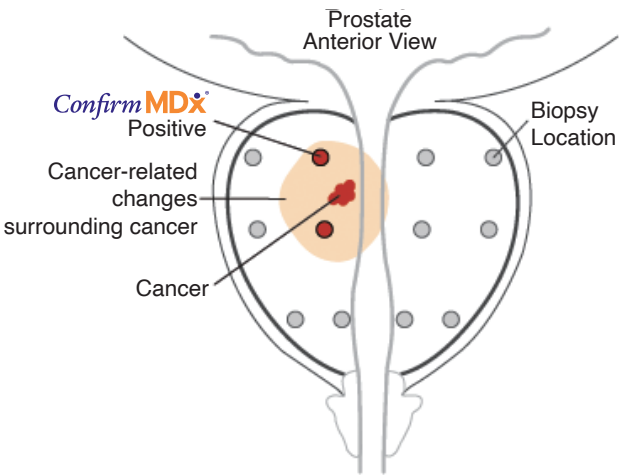
## Do You Have Undetected Prostate Cancer?

The ConfirmMDx test examines your biopsy tissue at the DNA level to detect cancer-related changes that can't be seen with a microscope.

A negative ConfirmMDx test result provides peace of mind that aggressive cancer was not missed with 96% certainty.<sup>5</sup>



## Get the Most Information Possible from Your Prostate Biopsy



### Why do you need ConfirmMDx?

ConfirmMDx will help determine if you are at risk for undetected prostate cancer. The test examines your biopsy tissue at the DNA level to detect cancer-related changes that cannot be seen during a standard microscopic evaluation.

### Can ConfirmMDx determine your risk for undetected cancer?

ConfirmMDx will provide you with valuable information about your risk for undetected prostate cancer. This additional information will give you peace of mind and confidence in the next steps after your prostate biopsy.

Because the test is performed on the existing biopsy samples, **no additional office visit or procedure** is required for your doctor to order ConfirmMDx.

### Will your insurance cover ConfirmMDx?

MDxHealth will work directly with your insurance provider to coordinate coverage. \$0 patient responsibility for Medicare. The vast majority of patients are responsible for \$250 or less.

### Questions about insurance?

Contact our Patient Advocate Team  
(866) 259-7001  
[PatientFirst@mdxhealth.com](mailto:PatientFirst@mdxhealth.com)

**ASK YOUR DOCTOR** if the ConfirmMDx test is right for you

**ConfirmMDx**  
for Prostate Cancer



**ConfirmMDx<sup>®</sup>**  
*for Prostate Cancer*

**helps  
identify  
undetected  
prostate  
cancer**

**ConfirmMDx<sup>®</sup>**  
*for Prostate Cancer*



(866) 259-5644



info@mdxhealth.com

MDxHealth is regulated under the Clinical Laboratory Improvement Amendments (CLIA) and College of American Pathologists (CAP) as an accredited laboratory to perform high complexity clinical testing. The ConfirmMDx for Prostate Cancer test was developed, and its performance characteristics determined by MDxHealth. It has not been reviewed by the U.S. Food and Drug Administration. The FDA has determined such clearance or approval is not necessary. The test is intended for use as an aid to clinicians for patient management decisions about the need for a prostate biopsy on men with clinical risk factors suggesting an increased risk for prostate cancer. Use outside of this indication has not been validated by MDxHealth. Test results should be interpreted in conjunction with other laboratory and clinical data available to the clinician and relevant guidelines on the decision for biopsy.

CLIA# 05D2033858; CAP# 8015399

References:

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- 2) Pinsky PF, et al. Repeat prostate biopsy in the prostate, lung, colorectal and ovarian cancer screening trial. BJU Int. 2007;99(4):775-779. doi:10.1111/j.1464-410X.2007.06708.x
- 3) Shen F, et al. Three-dimensional sonography with needle tracking: role in diagnosis and treatment of prostate cancer. J Ultrasound Med. 2008;27(6):895-905. doi:10.7863/jum.2008.27.6.895
- 4) Cancer Stat Facts: Prostate Cancer. Surveillance, Epidemiology, and End Results (SEER) Program website. Accessed June 2020. <https://seer.cancer.gov/statfacts/html/prost.html>
- 5) Van Neste L, et al. Risk score predicts high-grade prostate cancer in DNA-methylation positive, histopathologically negative biopsies. Prostate. 2016;76(12):1078-1087. doi:10.1002/pros.23191

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**What to  
Know  
Before  
Your  
Prostate  
Biopsy**

**ConfirmMDx<sup>®</sup>**  
*for Prostate Cancer*

**Up to  
30% of men  
with a  
negative  
biopsy result  
actually  
have cancer<sup>1,2</sup>**

Accurately detecting prostate cancer can be challenging. Cancer may be present in the areas of your prostate not biopsied.